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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/580,770

05/24/2007

Gloria Astrid Limb

GJE.1057

7263

23557 7590 01/05/2011
SALIWANCHIK LLOYD & SALIWANCHIK
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EXAMINER

CROUCH, DEBORAH

ART UNIT

PAPER NUMBER

1632

NOTIFICATION DATE

DELIVERY MODE

01/05/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

euspto@slspatents.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/580,770 | LIMB ET AL. | |
| | Examiner | Art Unit | |
| | Deborah Crouch | 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-6, 8, 11-13 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 11 -13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/3/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed August 31, 2010 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1, 2, 4-6, 8, 11-13 and 16 are pending. Claims 8 and 11 -13 are withdrawn from consideration as to a non-elected invention. Claims 1, 2, 4-6 and 16 are examined herein.

Prosecution of this applicant is now assigned to Deborah Crouch, Ph.D., AU 1632.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kelley et al. Invest. Ophthal. Vision Sci., 1995, Vol. 36, pp. 1280-1289.

Kelley teaches a composition of human fetal retinal progenitor cells cultured on Matrigel™ (page 1281, col. 1, parag. 1, lines 23-30). Whereas the human retinal progenitor cell composition taught by Kelley was produced by a materially different and

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separate method, there is no discernable structure that would permit distinction between the composition of Kelley and that claimed. Alternatively, any differences do not affect the structure or function of the present composition in view of the composition taught by Kelley. Therefore, Kelly anticipates the composition claimed.

Claim 6 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Walcott et al. Clinical Expert. Ophthalm., 2003, Vol. 31, pp. 246-249.

Walcott teaches a composition, the fetal eye, comprising human fetal retinal progenitor cells (page 246, col. 2, parag. 2). Whereas the human retinal progenitor cell composition taught by Walcott was produced by a materially different and separate method, there is no discernable structure that would permit distinction between the composition of Walcott and that claimed. Alternatively, any differences do not affect the structure or function of the present composition in view of the composition taught by Walcott. Therefore, Walcott anticipates the composition claimed.

Claims 1, 4 and 5 rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kelley et al. Invest. Ophthalm. Vision Sci., 1995, Vol. 36, pp. 1280-1289.

Kelley teaches the culture of human fetal retinal cells on Matrigel™ coated tissue culture plates in media containing EGF (page 1282, col. 2, parag. 3, lines 1-6). The retinal cells are described as comprising Muller cells, which would inherently be differentiated to a progenitor phenotype. Further, Kelley cultures the retinal cells comprising Muller cells in media comprising retinoic acid where they exhibit the expression of recoverin, a protein associated with photoreceptor cells (page 1284, col.

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1, parag. 3, lines 1-8 and col. 2, parag. 1, lines 1-5). A comparison of the claimed methods and those of Kelley indicate they are identical. Thus, Kelley clearly anticipates the claimed invention.

Products, known in the art at the time of filing, claimed to be produced by a new method, are not patentable unless a novel, nonobvious trait or characteristic is given the product by the new method. Such is the present situation. The claims are directed to differentiated cells and animals produced by the claimed method. However, neither the claims nor the specification indicate any novel or nonobvious feature given the cells or the animals not present in the cells and animals known in the art at the time of filing.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See also *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), *In re Ludtke*, 441 F.2d 660, 169 USPQ 563 (CCPA 1971), *Northam Warren Corp. v. D. F. Newfield Co.*, 7 F. Supp. 773, 22 USPQ 313 (E.D.N.Y. 1934) and MPEP 2112.01.

Claims 1, 2 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Limb et al, Investig. Ophthalm. & Visual Sci., 2002, Vol. 43, pp. 864-869 (IDS, filed 11/3/10, Ref. R1) in view of Kelley et al. Invest. Ophthalm. Vision Sci., 1995, Vol. 36, pp. 1280-1289.

Limb teaches a culture of adult human Muller cells expressing markers EGF-R, glutamine synthetase, CRALBP and α -SMA (page 866, col. 1, parag. 1, lines 2-8). Limb also teaches the culture of adult Muller cells on fibronectin (page 865, col. 1, parag. 3, lines 1-6).

Kelly teaches the culture of human fetal retinal cells on Matrigel™ coated tissue culture plates in media containing EGF (page 1282, col. 2, parag. 3, lines 1-6). The retinal cells are described as comprising Muller cells, which would be de-differentiated to a progenitor phenotype. Kelley offers motivation in stating human fetal retinal progenitor cells can be used to identify molecules involved in factors that control retinal neurogenesis.

Thus at the time of the instant invention, the ordinary artisan would have found it obvious to culture fetal or adult Muller cells, as taught by Limb et al and Kelley et al on matrigel or fibronectin matrix in the presence of EGF to determine the effect of such culture on cell morphology. Applicant is advised that amendment of the claims to include specific mythology would aid the withdrawal of this rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

November 22January 3, 2011